In re National Prescription Opiate Litigation: MDL 2804
Summary Sheet of Concise Issues Raised

Opposition Name: Plaintiffs' Opposition to Teva and Actavis Generic Defendants' Motion for Summary Judgment

Opposing Parties: Plaintiffs Summit County and Cuyahoga County

Issue 1: Have the Teva Defendants established there is no triable issue of fact regarding the Plaintiffs' false marketing claims?

Answer: No.

Plaintiffs have set forth evidence demonstrating that the Teva Defendants have marketed and sold two extremely powerful fentanyl-based brand opioids (Actiq and Fentora) as well as many generic opioids. They have already pled guilty to criminal acts taken in the 2000's when creating the market for Actiq, their fentanyl-based lollipop, and were required to pay $425 million to settle civil claims. In the criminal plea, the Teva Defendants admitted they knowingly failed to disclose the true risks of the drug to patients and prescribers.

The Teva Defendants continued the fraud in a campaign to shift demand from Actiq to Fentora which was approved only for "breakthrough ***cancer*** pain" in "opioid tolerant" patients, but was widely marketed for all "breakthrough pain." Like Actiq, Fentora was a huge success. The Teva Defendants created the market for Fentora using a variety of false statements disseminated through branded and unbranded marketing strategies. Defendants still sell a wide swath of opioids today, and still benefit from the fraudulent statements that made and maintained the broad market for these drugs. Specifically, the Teva Defendants have funded various "front groups," outsourcing their false marketing to seemingly neutral entities funded by big pharma.

Issue 2: Have the Teva Defendants established there is no triable issue of fact regarding the Plaintiffs' Suspicious Order Monitoring ("SOM") claims?

Answer: No.

Plaintiffs have set forth evidence demonstrating that Teva's DEA-required SOM systems were, and are, woefully insufficient. Internal documents and witness testimony support that the bare-bones system Teva and its predecessors had in place utterly failed to detect and halt suspicious orders. Teva offers no defense of any of its systems, and has put forth no expert to support them.

Defendants also argue summarily that no issue of fact exists regarding proximate causation, public nuisance, conspiracy, the opioid supply chain enterprise and statute of limitations. Each of these arguments lacks merit for reasons explained in Plaintiffs' opposition and in numerous other summary judgment briefs, affirmative and in opposition, filed by Plaintiffs and incorporated herein by reference. Summary judgment should be denied.

Filing Date: June 28, 2019

Response Date: July 31, 2019

Reply Date: August 16, 2019

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF OHIO

EASTERN DIVISION

In re NATIONAL PRESCRIPTION OPIATE LITIGATION	No. 1:17-md-2804
	Judge Dan A. Polster
This Document Relates To: TRACK ONE CASES.	

PLAINTIFFS' MEMORANDUM IN OPPOSITION TO
TEVA AND ACTAVIS GENERIC DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

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STATUTES, RULES AND REGULATIONS

Plaintiffs respectfully submit the following brief in response to the Teva and Actavis Generic Defendants' Motion for Summary Judgment (Dkt. #1784) ("Teva Mem."). Defendants argue that Plaintiffs have no evidence that they engaged in false marketing or failed to monitor and prevent the shipment of suspicious orders, at least not within the statute of limitations ("SOL"). They further argue that Plaintiffs lack any evidence to show that Teva's conduct caused them any harm. Defendants' causation argument is addressed in Plaintiffs' Consolidated Memorandum in Opposition to Defendants' Motions for Summary Judgment on Proof of Causation ("Causation Opp."), incorporated herein by reference. Here, Plaintiffs document that, contrary to Teva's contentions, they have considerable evidence of both fraudulent marketing efforts and inadequate controls against diversion of suspicious orders, beginning many years ago and continuing well past the date that would trigger any SOL defense. Plaintiffs' evidence is at least sufficient to give rise to a genuine dispute of material facts on these points, and thus Defendants' motion for summary judgment must be denied.

I. INTRODUCTION AND FACTUAL BACKGROUND

Teva[1] would have this Court believe it played a miniscule role in fueling the opioid epidemic facing Cuyahoga and Summit Counties ("CT1") and the nation at large. It asserts its brand drugs Actiq and Fentora were responsible for just ".03% of . . . opioid prescriptions in [CT1] from 2006 to 2016."[2] In fact, it sold **REDACTED** morphine milligram equivalents (MMEs) in CT1 from 2006 to 2014 – the eighth highest among all labelers.[3] Teva is anything but a small player. It holds itself out as the "World's

[1] Teva Pharmaceutical Industries Ltd. ("Teva Ltd."), Cephalon, Inc. ("Cephalon") and Teva Pharmaceuticals USA, Inc. ("Teva USA") are referred to herein as the "Teva Defendants." The "Actavis Generic Defendants" are a group of entities Teva bought from Allergan plc in 2016 and include: Watson Laboratories, Inc., Actavis LLC, Actavis Pharma, Inc., Warner Chilcott Company, LLC, Actavis South Atlantic LLC, Actavis Elizabeth LLC, Actavis Mid Atlantic LLC, Actavis Totowa LLC, Actavis Kadian LLC, Actavis Laboratories UT, Inc. f/k/a Watson Laboratories, Inc.-Salt Lake City and Actavis Laboratories FL, Inc. These entities are collectively referred to as the "Teva," "Defendants," or the "Teva Defendants." Citations are omitted and emphasis is added throughout, unless otherwise noted.

[2] Teva Mem. at 1-2.

[3] *See* Second Supplemental Report of Craig J. McCann, Ph.D., CFA, Dkt. #2000-16 at 4 (ranking top 20 labelers form 2006-2014).

Largest Medicine Cabinet," touting its "sales in approximately 100 global markets"[4] with revenues of $18.9 billion last year.[5] Its products filled "one in six" opioid prescriptions in the United States.[6]

Defendants' further suggestion that they had essentially no generics line until 2016 is simply false.[7] Teva USA has sold generic opioids as far back as 1980 and has sold Schedule II opioids starting in 1997, including generic OxyContin since 2005.[8] The Teva Defendants' 2016 acquisition of the Actavis generic business from Allergan plc made them the ***single largest prescription generic opioid maker*** in the United States.

Defendants' discussion of the marketing of Actiq and Fentora (their two fentanyl-based brand name drugs) also distorts the facts. Both drugs were approved only for opioid-tolerant "cancer patients" suffering "sharp spikes of severe pain." Defendants assert that "given their narrow indication," Actiq and Fentora were "not widely prescribed."[9] But at its peak, Actiq was generating annual revenues of more than a half-billion dollars and, in 2007, the FDA noted that Fentora was the fourth most commonly-dispensed fentanyl product from pharmacies nationwide.[10] The Teva Defendants accomplished this measure of success by largely flouting the FDA's "narrow indication." Indeed, in 2008, Defendant Cephalon, Inc. ***pled guilty*** to the illegal marketing of Actiq and paid $425 million to federal and state governments to resolve 2001-2006 Medicare fraud claims involving the sales and marketing of Actiq and other drugs. Additionally, when Actiq's patent expired and generic competition set in, Defendants pushed doctors to switch from Actiq to Fentora despite the fact that more than 90% of Actiq prescriptions were for non-cancer, off-label conditions, for which neither Actiq nor Fentora were approved.[11] Defendants later sought to expand the Fentora label, but the FDA rejected the plan

4 Ex. 1 (https://www.tevapharm.com/about/history/) at 37.
5 Ex. 2 (2018 Financial Results from Teva Website) (Herman Ex. 17).
6 Ex. 3 (TEVA_MDL_A_00455086) (Teva Opioid Market Share Calculations 2012-2016).
7 Teva Mem. at 1-2.
8 *See* Ex. 4 (TEVA_MDL_A_00455201) (list of Teva "Opioid Containing Products").
9 Teva Mem. at 1.
10 Ex. 5 (2007 Fentora Marketing Plan) (TEVA_MDL_A_00360932) at 45; Ex. 6 (TEVA_MDL_A_02893899) at 967.
11 Ex. 7 (TEVA_MDL_A_00375244) (2008 Fentora Marketing Overview PowerPoint ("PPT")); Ex. 8 (TEVA_MDL_A_0000368405) (2005-2006 FEBT Marketing Plan); Ex. 9 (TEVA_MDL_A_02376171) (2006 Pyfer Email

because the company did not address the "increased abuse, misuse, overdose and addiction that is to be expected" with broader prescribing.[12]

The Teva Defendants also maximized sales by sponsoring major, unbranded-marketing efforts through opioid front groups, including by sponsoring the American Pain Foundation's ("APF") publications: *Treatment Options: A Guide for People Living with Pain*, and *Exit Wounds*, both of which misled potential patients by assuring that opioid addiction was rare and typically caused by the aberrant behavior of patients, not by the drugs. These and other efforts were instrumental in shifting the public's and prescribers' perception of opioids as dangerous and only appropriate in limited situations to being safe and effective for all types of pain, which ultimately fueled the epidemic we face today.

Compounding matters, and as detailed in one of Plaintiffs' affirmative motions for partial summary adjudication,[13] Defendants wholly failed to comply with their duties under the Federal Controlled Substances Act by failing to report and suspend shipments of suspicious orders.[14] The Teva Defendants ignored repeated warnings that their suspicious order monitoring ("SOM") systems were noncompliant with the law and failed to implement much-needed improvements.[15] Indeed, in mid-2012, a former DEA agent evaluated the Teva SOM system, finding it had "no formal Standard Operating Procedures or official guidelines," its "due diligence" procedures provided little useful information and its computer program was "rudimentary" and "not sufficiently sensitive [to provide] any meaningful analysis."[16] Up to that date, Teva's system had ***never*** identified a suspicious order and Teva had ***never*** reported a suspicious order to the DEA.[17] Defendants slow-rolled any change, taking two and one-half

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with Attached Accelanyl Commercial Needs PPT); Ex. 10 (TEVA_MDL_A_07846839) (2007 Fentora Strategic Marketing Plan); Ex. 5 (2007 Fentora Marketing Plan).

12 Ex. 11 (2008 FDA Fentora Non-Approvable Letter) (TEV_FE00116840) at 840.

13 *See* Plaintiffs' Memorandum of Law in Support of Motion for Partial Summary Adjudication that Defendants Did Not Comply with Their Duties under the Federal Controlled Substances Act to Report Suspicious Opioid Orders and Not Ship Them (Corrected) (Dkt. #1924, "Ps' CSA Mem.").

14 Ps' CSA Mem.

15 *Id.* at 40-43.

16 Ex. 12 (TEVA_MDL_A_01060005) at 005-006 (Sept. 25, 2012 Buzzeo/Cegedim Report).

17 *Id.* at 005, 007.

years (until August 2014) to implement a set of just five rudimentary policies for a new system.[18] And even that system was inadequate: Teva's own internal auditors found it to be dangerously understaffed.[19] Teva has neither added sufficient staff nor sought to substantially improve its system since 2015, but rather maintains a bare-bones system largely reliant on conflicted sales representatives (who are compensated based on sales) to help flag or halt the suspicious orders. These acts, and others, demonstrate that Defendants' first priority is and always has been to maximize opioid sales irrespective of their obligations under the law.

II. TEVA'S RELEVANT CORPORATE HISTORY AND ORGANIZATIONAL STRUCTURE

Teva did not invent the opioid products at issue here but rather joined into the market by buying opioid businesses or by producing generic versions of successful opioid drugs.[20] Actiq, originally owned by the Anesta Corp. ("Anesta"), was FDA-approved on November 4, 1998.[21] In 2000, Cephalon bought Anesta, and in 2008, Cephalon introduced Fentora, Actiq's successor. In 2011, Teva USA acquired Cephalon and its opioid products Actiq and Fentora.[22]

Foreign Defendant Teva Ltd., an Israeli-based global pharmaceutical company, is the parent corporation. Teva Ltd. exerts managerial and financial control over the domestic Teva movants here.[23] Teva Ltd. controls its subsidiaries through a global operation, with Teva Ltd.'s CEO designated as the "Chief Operating Decision Maker." All officers and employees of Teva Ltd.'s subsidiaries report

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[18] *See* Ex. 13 (TEVA_MDL_A_02660925); Ex. 14 (TEVA_MDL_A_02660932); Ex. 15 (TEVA_MDL_A_02660892); Ex. 16 (TEVA_MDL_A_01061094).

[19] Ex. 17 (TEVA_MDL_A_02475564) at 570.

[20] Ex. 18 (TEVA_MDL_A_02419959) (Opioid Products First Month of Sales) (Fahey Ex. 1).

[21] Ex. 19 (TEVA_MDL_A_08242688) (1998 Actiq Approval Letter).

[22] Ex. 20 (2011 Teva Press Release re Cephalon Acquisition); Ex. 21 (2011 Teva Press Release Announcing Cephalon Acquisition); Ex. 22 (2011 Teva Press Release re FTC Approval of Cephalon Acquisition).

[23] Defendants argue that summary judgment should be granted as to Teva Ltd. because there is no evidence of "independent conduct" by the entity. Teva Mem. at 5 n.8 (emphasis omitted). This is incorrect. As detailed in Plaintiffs' Opposition to Teva Pharmaceuticals Industries Ltd.'s Motion to Dismiss for Lack of Personal Jurisdiction (Dkt. #1815, "Opp. to Teva Ltd. MTD"), the evidence demonstrates that Teva Ltd. shares a corporate history, structure, management and officers with Teva USA and Cephalon, shares a complex financial system and controls and manages the day-to-day activities of the subsidiaries. Opp. to Teva Ltd. MTD at 4-17. As that brief shows, Teva Ltd., via the six U.S. members of the Executive Management Team and others, took part in or oversaw the actions that have led to liability in this case. *See* Opp. to Teva Ltd.'s MTD and related Declarations of Mark Crawford and Alex Fahey. Dkt. #'s 1816, 1817.

ultimately to the 12 corporate officers on Teva Ltd.'s Executive Management Committee (6 of whom are based in the United States), who in turn report to Teva Ltd.'s CEO.[24] Teva's organizational structure is such that all Teva entities are "integrated into one commercial organization."[25]

In 2016, Teva Ltd. acquired the Actavis Generic Defendants from Allergan, Inc. greatly expanding its reach into generic opioid products.[26]

III. THE EVIDENCE WARRANTS DENIAL OF SUMMARY JUDGMENT

Summary judgment may only be granted where "'there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.'" *Baynes v. Cleland*, 799 F.3d 600, 606 (6th Cir. 2015) (quoting Fed. R. Civ. P. 56(c)). In examining the motion, the Court must "review the facts in the light most favorable to" the non-moving party. *Kalamazoo Acquisitions, L.L.C. v. Westfield Ins. Co., Inc.*, 395 F.3d 338, 342 (6th Cir. 2005). As shown below, the record demonstrates that triable issues of fact exist with regard to the defendants' liability and that this case should proceed to the jury.

A. Cephalon and Teva Created Market Demand Through Criminal Acts and Fraudulent Marketing

1. 1998-2006: Actiq's Criminal Marketing Scheme

As Defendants admit, the FDA approved Actiq in 1998 solely for the management of "breakthrough pain" in opioid-tolerant cancer patients.[27] The FDA restricted the drug's use because Actiq was a powerful narcotic, fentanyl, in the form of a fast-dissolving lollipop, also known as a Transmucosal Immediate-Release Fentanyl product ("TIRF").[28] Actiq's sudden and potent dose of fentanyl presented increased risk of misuse, abuse, addiction and overdose, thus the FDA required Actiq's then-owner, Anesta, to agree to a Risk Minimization Action Plan ("RiskMAP") to ensure doctors

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[24] Teva Ltd.'s 2018 "Segment Memorandum" reports that its business "will continue to be managed and orchestrated by Teva's CEO, who . . . is directly involved in assessing performance and making decisions on overall resource allocation, and ultimately responsible for the allocation of resources." Ex. 23 (TEVA_MDL_JD_000839) at 841.

[25] *Id.* at 842.

[26] *See* Ex. 4 (TEVA_MDL_A_00455201) (list of Teva "Opioid Containing Products"); Ex. 24 (Teva-Herman-014) & Ex. 25 (Teva-Herman-015) (Teva press releases announcing Teva's acquisition of Allergan's generic business including the Actavis Generic Entities and Anda, Inc., a major drug distributor which is also a defendant in this litigation for its distribution of opioid products).

[27] Teva Mem at 1. *See also* Ex. 19 (TEVA_MDL_A_08242688) (1998 Actiq Approval Letter).

[28] *Id.*

fully understood its risks before prescribing the drug.[29] The RiskMAP required Anesta to proactively educate doctors on the narrow indication and risks, and dictated and tightly controlled the marketing messages for the drug.[30] Any plans to market the drug had to abide by the RiskMAP and the FDA's subsequent regulations.[31]

In 2000, Actiq generated a relatively modest $16 million in revenue for its then-owner Anesta.[32] That same year Cephalon purchased Anesta.[33] Cephalon set extremely high sales goals for Actiq, pressuring employees to generate volume sales. The pressure tactics worked spectacularly well. By 2006, Cephalon's Actiq sales were $590.7 million, more than 36 times the amount sold in 2000.[34] The massive increase in sales was driven largely by fraudulent marketing, *i.e.*, criminal acts later admitted by Defendants, which resulted in the guilty plea and $425 million in fines and settlements.[35] Cephalon and its successors were also required to adhere to a five-year "Corporate Integrity Agreement" governing marketing practices.[36]

Cephalon's Actiq scheme originated with its written "Master Plan" from 2000 that recognized both the drug's small market share for its limited, approved, cancer indication and its massive potential for growth for chronic pain and other non-cancer uses.[37] The plan set out to market the drug far beyond oncologists and pain specialists who primarily treated cancer patients.[38] For example, rather than emphasize Actiq's indication for "breakthrough ***cancer*** pain" ("BTCP"), the company switched to promote Actiq as being safe and effective for use in any "Breakthrough Pain" or "BTP."[39] The company

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29 Ex. 19 (TEVA_MDL_A_08242688) (1998 Actiq Approval Letter); Ex. 26 (TEVA_MDL_A_03272088) (Aug. 1, 2001 Actiq RiskMAP).

30 *Id.*

31 Ex. 27 (Summary of RiskMAP accompanying FDA Fentora approval documentation; Actiq's successor Fentora, which was approved in 2006 with a similar RiskMAP); Ex. 28 (2017 Fentora RiskMAP).

32 Ex. 29 (TEVA_MDL_A_05666277) (2006 Actiq Marketing Sales Training PPT).

33 Ex. 30 (*Marketwatch* article, Cephalon to buy Anesta for $444 million, July 17, 2000).

34 *Id.*

35 Ex. 31 (DOJ Press Release re Cephalon Guilty Plea); Ex. 32 (Cephalon Guilty Plea Agreement).

36 Ex. 33 (Corporate Integrity Agreement); Ex. 34 (Government Sentencing Memorandum); Ex. 35 (Sept. 29, 2008 DOJ Press Release); Ex. 32 (Cephalon Guilty Plea Agreement).

37 Ex. 36 (TEVA_MDL_A_01159082) (2000 Actiq Master Plan).

38 *Id.* at 085-086, 131-133.

39 Ex. 37 (TEVA_MDL_A_01159143) at 175 (2001 Actiq Marketing Plan).

also sought to convince these new doctors that Actiq's potential for abuse and addiction was minimal.[40] The original 2000 Master Plan was the basis for Cephalon's Actiq marketing up to 2006, when the company started transitioning its stable of doctors and patients to Fentora.[41]

The fraudulent marketing plan was wildly successful: Although the cancer-only FDA limitation for the drug never changed, by the time Actiq started facing generic competition in 2006 the share of non-cancer patients taking the drug was no different than for other opioids on the market that did not have a cancer-only indication.[42] It was also illegal. As much as the 2000 Master Plan was the basis for Cephalon's marketing through 2006, it was also the basis for the U.S. Government's prosecution of the company and Cephalon's guilty plea.[43] As the guilty plea recites, Cephalon acknowledged that with regard to marketing, Actiq's label "did not bear adequate directions for each of the drug's intended uses."[44]

In an attempt to encourage the substitution of its product with competitor products, Actiq consultant meetings educated doctors on the use of Actiq for use in afflictions such as chronic back pain, arthritis and migraine headache.[45] Addiction was discussed at these meetings by Dr. Jeffrey Gudin and doctors left with the impression that "ACTIQ is safer than I thought it was."[46]

2. 2003-2007: Cephalon Ignores Its Internal Compliance Officer's Report that the Marketing Department Had Violated Actiq RiskMAP Terms

Cephalon's skirting of the law was not limited to the Actiq marketing plans. It also fought hard to keep employees from alerting the FDA about internal bad acts at the company.

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40 *Id.*

41 Ex. 37 (TEVA_MDL_A_01159143) (2001 Actiq Marketing Plan); Ex. 38 (TEVA_MDL_A_05313123) (2001 Actiq Marketing PPT for National Sales Meeting); Ex. 39 (TEVA_MDL_A_00454816) (2002 Actiq Marketing Plan); Ex. 40 (TEVA_MDL_A_05965744) (2002 Actiq Marketing Plan PPT from Pyfer); Ex. 41 (TEVA_MDL_A_05734046) (2002 Actiq Sales Training PPT); Ex. 42 (TEVA_CHI_00042882) (2003 Actiq Marketing Plan); Ex. 43 (TEVA_CHI_00042951) (2004 Actiq Marketing Plan); Ex. 44 (TEVA_CHI_00043010) (2005 Actiq Marketing Plan); Ex. 29 (TEVA_MDL_A_05666277) (2006 Actiq Marketing Sales Training PPT).

42 Ex. 5 (2007 Fentora Marketing Plan).

43 Ex. 33 (Corporate Integrity Agreement); Ex. 34 (Government Sentencing Memorandum); Ex. 35 (Sept. 29, 2008 DOJ Press Release); Ex. 32 (Cephalon Guilty Plea Agreement).

44 Ex. 32 (Cephalon Guilty Plea Agreement) at 4-5.

45 Ex. 45 (TEVA_MDL_A_09591982).

46 *Id.* at 986.

For example, the fraudulent marketing became so egregious that its public relations and grant coordinator, Stacey Beckhardt, went to her supervisor to express concerns about the marketing department's tactics, but her warnings were ignored.[47] Further, in early 2003, its internal compliance auditor, David Brennan, was assigned to audit the company's compliance with Actiq's "RiskMAP."[48] Brennan's October 2003 audit report made clear that Cephalon was not complying with the RiskMAP requirements, including the requirement that Cephalon conduct customer surveys of four pharmacy companies that sold Actiq.[49] Indeed, only one survey was finished, showing that a large percentage of new patients were not receiving "Welcome Kits" as required to help them understand the risks the drug presented.[50] Survey results also showed that the drug was clearly being overly-marketed to non-cancer doctors and raised other issues.[51]

Brennan's boss told him not to distribute the report,[52] and then, on February 12, 2004, Brennan was fired. Cephalon offered him a severance package, but Brennan refused it.[53] Later that month, Brennan wrote to the FDA that he was "aware of several issues but the most important, and the one for which [he] believe[d] [he] was terminated regards the Actiq (oral Fentanyl Citrate on a stick) Risk Management Program."[54] Brennan also wrote that he believed Cephalon management was aware of Actiq-related issues and had not taken action to correct them.[55]

In early June 2004, the FDA contacted Cephalon, expressing "that high levels of FDA are very concerned about information that they have analyzed that reflect staggering off-label use and increasing

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47 Ex. 46 (Beckhardt Tr.) at 266:7-267:15.

48 Ex. 47 (TEVA_MDL_A_01159577) (Brennan Draft Audit Report); Ex. 26 (TEVA_MDL_A_03272088) (Aug. 1, 2001 Actiq RiskMAP).

49 Ex. 47 (TEVA_MDL_A_01159577) (Brennan Draft Audit Report).

50 Ex. 48 (Marchione Tr.) at 130:15-139:8; Ex. 49 (TEVA_MDL_A_04578988) (Actiq RMP Quarterly Report from April 1, 2003 to June 30, 2003).

51 *Id.*

52 Ex. 47 (TEVA_MDL_A_01159577) (Brennan Draft Audit Report); Ex. 50 (Brennan_002128) (RMP Meeting Notes from Brennan).

53 Ex. 51 (Brennan_002235) (Feb. 12, 2004 Unsigned Brennan Termination of Employment Memo).

54 Ex. 52 (Brennan Letter to the FDA).

55 *Id.*

reports of diversion, misuse and unintended pediatric use of Actiq."[56] This was followed up by a June 29, 2004 letter requesting a meeting to discuss its concerns about fraudulent marketing, abuse and diversion of Actiq and possible non-compliance by Cephalon with the Actiq RiskMAP program.[57] The FDA was "particularly concerned that Actiq be promoted . . . only to its appropriate target audience" and sought information about Cephalon's "unbranded 'disease awareness' materials."[58] At an August 30, 2004 meeting, the FDA expressed major concerns with the materials Cephalon had presented and the manner in which it was marketing Actiq.[59] The FDA was especially concerned: that Cephalon was targeting non-cancer doctors; that sales representatives were opening their sales calls focusing not on Actiq's limited indication for "BTCP," but on "BTP" generally; that Cephalon had downplayed the serious addiction and abuse risks associated with Actiq; and that Cephalon's use of "disease awareness materials" in promoting the drug was "an indirect way to promote or solicit questions on off-label uses."[60] Despite the FDA's expression of strong concerns about Cephalon's inappropriate marketing techniques, Cephalon continued with its fraudulent promotion of Actiq.[61]

These improper sales tactics reached into Ohio. For example, Laura Sippial, an Ohio sales representative with Cephalon from 2001 to fall 2010, often called on doctors with specialties other than oncology or pain specialists, and none of her supervisors ever raised any concern with calling on doctors who were not pain specialists or oncologists.[62]

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56 Ex. 53 (TEVA_MDL_A_08242371) (Marchione Email and June 3, 2004 Contact Report).

57 Ex. 54 (TEVA_MDL_A_03317918) (2004 Letter from FDA Requesting Meeting and Concerns re Off-Label Promotion).

58 *Id.* at 918-919.

59 Ex. 55 (TEVA_MDL_A_01584978) (2005 DDMAC Meeting Minutes and Concerns re Off-Label Promotion).

60 *Id.* at 983.

61 *See, e.g.*, Ex. 56 (TEVA_MDL_A_07424105) (Sept. 29, 2004 DDMAC Letter); Ex. 57 (TEVA_MDL_A_00267691) (Nov. 24, 2004 DDMAC Letter); Ex. 58 (TEVA_MDL_A_01583546) (Nov. 29, 2005 DDMAC Letter); Ex. 43 (TEVA_CHI_00042951) (2004 Actiq Marketing Plan) at 15-21, 24, 29, 33-34, 35-40; Ex. 44 (TEVA_CHI_00043010) (2005 Actiq Marketing Plan) at 14-20, 20-23, 40-46, 47-52, 55-60; Ex. 29 (TEVA_MDL_A_05666277) (2006 Actiq Marketing Sales Training PPT) at slides 9, 10, 22, 26, 28, 33-35, 37.

62 Ex. 59 (Sippial Tr.) at 15:13-24, 98:1-98:6, 98:18-99:7.

Cephalon had affirmatively trained its sales force to disregard the restrictions of the FDA-approved label and to fraudulently promote the drugs for off-label uses.[63] Cephalon also structured its sales quotas and bonuses in such a way that sales representatives could reach their sales goals only if they promoted and sold the drugs for a wide variety of pain uses for which the drug was not approved.[64]

Beyond these practices, Defendants also paid third parties to encourage the general use of opioids and conducted other unbranded marketing. Teva, for example, sponsored the APF guide *Treatment Options: A Guide for People Living with Pain* (2007), which teaches that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft.[65] Additionally, the guide falsely advises that "[r]estricting access to the most effective medications for treating pain is not the solution to drug abuse or addiction."[66] It further states that referring to opioids as narcotics "reinforces myths and misunderstandings as it places emphasis on their potential abuse rather than on the importance of their use as pain medicines."[67] Opioids are narcotics, and their abuse potential is anything but a "myth."

As detailed in Plaintiffs' Memorandum in Opposition to "Generic Manufacturers" Motion for Partial Summary Judgment, Teva had numerous other unbranded marketing tactics as well. For example, Teva made large payments to third-party pain groups for their advocacy on pain and opioid products[68] while hiding its affiliation with these groups;[69] Teva made substantial payments to speakers who promoted its unbranded marketing scheme;[70] Teva made educational grants to promote the use of opioids for chronic pain;[71] Teva worked behind the scenes to water down legislation combatting the

63 Ex. 31 (DOJ Press Release re Cephalon Guilty Plea); Ex. 32 (Cephalon Guilty Plea Agreement).
64 *Id.*
65 Ex. 60 (TEVA_MDL_A_01090496).
66 *Id.* at 518.
67 Id. at 514.
68 Ex. 61 (TEVA_MDL_A_08653780).
69 Ex. 62 (TEVA_MDL_A_01207133) (PPT falsely stating American Pain Foundation is "[a]n independent, nonprofit organization serving people with pain through information, advocacy and support") (emphasis omitted).
70 Ex. 63 (TEVA_MDL_A_06788866).
71 Ex. 64 (*see, e.g.*, (TEVA_MDL_A_02481967).

opioid epidemic and curbing the use of opioids;[72] Teva made large payments for the dissemination of unbranded pain publications with misleading messaging, such as *Exit Wounds* and *Pain Matters*;[73] Teva spread its unbranded and disease awareness (pain) marketing messages at major professional conferences;[74] and Teva actively recruited and paid key opinion leaders to spread its marketing messages.[75]

Teva even had a handbook entitled *Teva Advocacy Mapping: Identifying Advocacy Partners to Enhance Patient Case*, which was intended as a roadmap for recruiting front groups to spread Teva and Cephalon's unbranded marketing messages advocating the use of opioids for the treatment of chronic pain.[76] The handbook scored numerous pain groups on a grid to gauge their "clout & strength," and provided a plan for Teva to engage each of the organizations and their "influencers" to spread their marketing messages.[77] *Id.*

3. 2004 -2011: Fentora Uses the Actiq Playbook

Actiq's patent was set to expire in 2006, which meant it would face low-cost generic competition from that date forward. The loss of more than a half-billion dollars in revenue hurt Cephalon and scared its sales staff.[78] The marketing group even prepared a maudlin "Actiq Eulogy" to bury the drug, noting that it "shot to stardom as the nemesis of BTP," and that "by the end of his all-too-short career, Actiq was a Superstar who had grossed nearly $1.8 billion and treated over 100 million BTP episodes."[79] And yet despite all the investigations and turmoil surrounding Cephalon's improper marketing, the staff gave Actiq "one last standing ovation" as they said "goodbye to our old friend."[80]

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72 Ex. 66 (TEVA_MDL_A_00694962).
73 Ex. 68 (TEVA_MDL_A_01088080); Ex. 70 (TEVA_MDL_A_01136278); Ex. 107 (TEVA_MDL_A_08657218).
74 Ex. 71 (TEVA_MDL_A_00886736).
75 Ex. 72 (TEVA_MDL_A_00877813); Ex. 65 (TEVA_MDL_A_08652122).
76 Ex. 74 (TEVA_MDL_A_00499645).
77 Ex. 75 (TEVA_MDL_A_00499646) at 652, 655.
78 Ex. 7 (TEVA_MDL_A_00375244) (2008 Fentora Marketing Overview PPT); Ex. 5 (2007 Fentora Marketing Plan).
79 Ex. 76 (TEVA_MDL_A_03237316) ("Actiq Eulogy").
80 *Id.*

At the same sales meeting, the sales staff was trained on how to market its new fentanyl-based opioid, Fentora. Cephalon had acquired the rights to Fentora in 2004, and it received FDA approval in September 2006.[81] The FDA bluntly rejected Cephalon's request to legitimize Fentora's use beyond cancer patients, specifically rejecting Cephalon's proposal to monitor, prevent and curb abuse of the drug. [82] Like Actiq, Fentora was approved only for BTCP in opioid-tolerant patients; and like Actiq, Fentora was approved under a very restrictive RiskMAP.[83]

Cephalon, however, pushed ahead with the transition, marketing Fentora almost the same way as Actiq.[84] The marketing plans also reflect Defendants were fully aware that most Actiq use was for non-cancer pain conditions.[85] The restricted approval meant more than ***90%*** of Fentora prescriptions would be for non-cancer uses if it was presented as an alternative to Actiq.[86]

The Fentora training manuals contained false and misleading statements used to teach the sales staff to market the drug. For example, one training guide stated that "[p]ain appears to reduce the euphoric effects of opioids, so people taking opioids to manage their pain may be at a lower risk for addiction" and that "[p]atients in pain do not usually become addicted to opioids."[87]

Indeed, in September 2007, after receiving numerous reports of serious adverse events, including deaths and prescribing to non-opioid tolerant patients, the FDA issued a Public Health Advisory regarding Fentora.[88] Also in 2007, Cephalon's auditors, Ernst & Young LLP, also found that Cephalon

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81 Ex. 77 (TEVA_MDL_A_02074924) (2006 Fentora Approval Letter).
82 Ex. 11 (TEV_FE00116840) (Fentora Not Approvable Letter re Addiction).
83 Ex. 77 (TEVA_MDL_A_02074924) (2006 Fentora Approval Letter).
84 Ex. 8 (TEVA_MDL_A_00368405) (2005-2006 FEBT Marketing Plan); Ex. 78 (TEVA_MDL_A_00556885) (FEBT Strategic Publication Plan); Ex. 5 (2007 Fentora Marketing Plan PPT).
85 Ex. 78 (TEVA_MDL_A_00556885) (FEBT Strategic Publication Plan); Ex. 79 (TEVA_MDL_A_00454816) (2002 Actiq Brand Plan); Ex. 8 (TEVA_MDL_A_00368405) (2005-2006 FEBT Marketing Plan); Ex. 43 (TEVA_CHI_00042951) (2004 Actiq Marketing Plan); Ex. 42 (TEVA_CHI_00042882) (2003 Actiq Marketing Plan).
86 Ex. 42 (TEVA_CHI_00042882) (2003 Actiq Marketing Plan) at 12 and 17; Ex. 44 (TEVA_CHI_00043010) (2005 Actiq Marketing Plan) at 16 & 25; Cephalon's 2007 marketing plan broke down the Actiq monthly prescriber percentages, noting that only 6% came from oncologists and only 8% of Actiq prescriptions overall were for cancer treatment. Ex. 5 (2007 Fentora Marketing Plan PPT).
87 Ex. 80 (TEVA_MDL_A_00890304) at 355.
88 Ex. 6 (TEVA_MDL_A_02893899) at 904.

was breaking the law and violating the "Risk-MAP" program in numerous ways.[89] By 2009, the FDA had issued a "DDMAC letter," noting that Fentora links on internet search engines were misleading because they promoted efficacy information but did not convey any information regarding risk; and the company's "sponsored links" did not adequately present Fentora's indication.[90]

4. 2011-Forward: Teva Continues the Fraud

In October 2011, the Teva Defendants closed on their $16 billion purchase of Cephalon and continued the company's marketing practices.[91] They studied and recognized the positive effect their messages had on Fentora prescribers, noting that "detailing" had return on investment levels of 500% in 2014 and always more than 100% going back to 2010.[92] There is no question that the Fentora salespeople (trained with the above-referenced false and misleading materials) targeted doctors in Cleveland and other parts of Ohio.[93]

The Teva Defendants also continued and expanded the Cephalon practice of funding front groups and speakers programs to promote false and misleading messaging and minimize the addiction and misuse risks associated with Fentora.[94] They also engaged their clinical communications department to ghost-write letters for doctors so they could submit them to insurers to override their decisions not to pay for non-cancer uses of Fentora.[95]

In December 2011, the Teva Defendants widely disseminated a journal supplement entitled *Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and*

89 *See* Ex. 81 (TEVA_MDL_A_06570130).

90 Ex. 82 (TEVA_MDL_A_04183493) at 495-496.

91 Ex. 83 (TEV_FE00037945) (2009 Fentora Brand Plan); Ex. 84 (TEVA_MDL_A_00363031) (2010 Fentora Brand Plan); Ex. 85 (TEVA_MDL_A_00556008) (2011 Fentora Brand Plan); Ex. 86 (TEVA_MDL_A_01211474) (2012 Fentora Brand Plan).

92 *See* Report of Professor Meredith Rosenthal, Dkt. #2000-023 at 31; Ex. 87 (TEVA_MDL_A_02767666) at 673; Ex. 115 (TEVA_MDL_A_00886031) at slide 19; Ex. 123 (TEVA_MDL_A_00556014) at slide 12.

93 *See, e.g.*, Ex. 88 (TEVA_MDL_A_11196054).

94 Ex. 65 (TEVA_MDL_A_00565051) (List of Grants from 2012-2016); Ex. 89 (Beckhardt Ex. 20); Ex. 90 (Beckhardt Ex. 23); Ex. 91 (Beckhardt Ex. 24); Ex. 92 (Beckhardt Ex. 25); Ex. 93 (Beckhardt Ex. 26); Ex. 94 (Beckhardt Ex. 27); Ex. 95 (Beckhardt Ex. 29); Ex. 46 (Beckhardt Tr.) at 33:10-34:10, 142:21-143:4.

95 Ex. 96 (TEVA_CHI_00001939) (Mar. 1, 2008 Approved Letter of Medical Necessity Template); Ex. 97 (TEVA_CHI_00001941) (Mar. 1, 2008 Letter of Medical Necessity Cover Letter); Ex. 98 (TEVA_CHI_00001967) (Letter of Medical Necessity for Lower-Back Pain); Ex. 99 (TEVA_CHI_00001976) (Letter of Medical Necessity for Chronic Neuropathic Pain); Ex. 100 (TEVA_MDL_A_01065540) (Mar. 24, 2008 Letter of Medical Necessity for Non-Cancer BTP); Ex. 101 (TEVA_CHI_00003304) (Mar. 7, 2008 Letter of Medical Necessity Template).

Oral Transmucosal Fentanyl Citrate (ACTIQ) to *Anesthesiology News*, *Clinical Oncology News* and *Pain Medicine News* – three publications that are sent to thousands of anesthesiologists and other medical professionals.[96] The special report openly promoted Fentora for "multiple causes of pain," and not just cancer pain.[97]

Defendants' claims that they are reformed citizens, that they stopped the fraudulent practices before 2012 (*see, e.g.*, Teva Mem. at 9-11), are baseless. Defendants created the market for Actiq and Fentora based on misstatements and fraud; their practices have not materially changed since they bought Cephalon in 2012, and they certainly have never sought to correct the misapprehensions they created.

After 2012, the Teva Defendants moved to funding front groups, *i.e.*, pain advocacy groups funded by big pharma, to promote opioids as safe and effective when they knew the opposite was true. For example, in 2014, Teva paid for the production of, and heavily promoted, a ghostwritten book by APF called *Exit Wounds* that targets veterans and falsely assures them that "[l]ong experience with opioids shows that people who are not predisposed to addiction are unlikely to become addicted to opioid pain medications."[98] Teva employees were seeking publicity for the author into 2015.[99]

Further, the Teva Defendants created a 2014-2015 video called *Pain Matters*, which ran as a documentary on the Discovery Channel, on the internet and at pain management conferences.[100] Teva's 2015 budget for the *Pain Matters* campaign was approximately $1 million, and Teva carefully tracked the results.[101] The *Pain Matters* campaign focused on the use of opioids for chronic pain with messages such as: "At Teva Pharmaceuticals, we understand that chronic pain affects more than 100 million

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96 Ex. 102 (TEVA_MDL_A_01208119).

97 *Id.* at 125.

98 Derek McGinnis, *Exit Wounds: A Survival Guide to Pain Management for Returning Veterans and Their Families* 106-107 (American Pain Foundation 2009) (also referring to opioids as the "'gold standard' of pain medications . . . often underused" due to "fear of addiction" and stating falsely that "[l]ong experience with opioids shows that people who are not predisposed to addiction are unlikely to become addicted to opioid pain medications").

99 Ex. 103 (TEVA_MDL_A_08649866).

100 Ex. 104 (Day Tr.) at 220:5-228:18; Ex. 105 (TEVA_MDL_A_02296564); Ex. 106 (TEVA_MDL_A_08657349).

101 Ex. 104 (Day Tr.) at 229:6-233:1; Ex. 107 (TEVA_MDL_A_08657218).

Americans. . . . Prescription opioid medications are an important part of a treatment plan for many people living with chronic pain."[102]

Teva continued to utilize Dr. Gudin's minimization of addiction in its *Pain Matters* marketing campaign. Dr. Gudin is featured on the *Pain Matters* website and cited a study by Dr. David Fishbain which found that "only 3.27 percent of patients being treated with chronic opioid therapy had a high likelihood of abuse or addiction with their opioid analgesics. Most notably, he found a 25 times lower rate of abuse or addiction in patients who didn't have a prior history of abuse or addiction . . . [risk is] relatively low for patients with chronic non-malignant pain who don't have a previous history of addiction."[103]

Cephalon and Teva's sales force continued to fraudulently market Fentora. According to Defendants' sales call database, between 2006 and 2015, the companies made a total of nearly 20,000 sales calls relating to Fentora in Ohio.[104] Teva's Ohio sales representatives provided detailed testimony about inappropriate conduct with regard to Teva's marketing of Fentora to Ohio doctors. For example, their sales representatives nominated doctors who were known to prescribe for non-cancer uses, to be Actiq and Fentora speakers in Ohio, including Dr. Riad Laham, and Dr. Steve Simon despite Dr. Simon's conviction for intentional distribution of controlled substances.[105] Valerie Kaisen, an Ohio sales representative with Cephalon and Teva from February 2001 until being laid off in 2017, testified that she relied on the company to properly vet physician speakers, but had not been made aware that certain speakers had, in fact, been convicted felons or were promoting overprescribing.[106]

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102 Ex. 108 (TEVA_Day_026) ("Pain Matters | Information & Resources for Chronic Pain").
103 Ex. 109 (TEVA_MDL_A_08657940) at 946.
104 Ex. 110 (TEVA_MDL_A_00763717) (Number of Fentora Sales Visits by Teva Each Year, 2006-2015).
105 Ex. 111 (Kaisen Tr.) at 194:13-202:14, 239:14-19.
106 *Id.* at 16:3-24, 203:13-204:22.

B. Defendants' SOM System Is and Always Has Been Non-Compliant with the Law

As detailed in Plaintiffs' Causation Opp., Defendants' suggestion that their deficient SOM systems are irrelevant because causation has not been established, is completely meritless.[107] Defendants do not even attempt to assert their SOM systems were fulsome, but rather suggest they had no obligation to review data which would identify suspicious orders.[108] As DEA registrants, each of these Defendants was, and is, required to build and maintain adequate safeguards against diversion of the controlled substances it made and sold. *See Masters Pharm., Inc. v. DEA*, 861 F.3d 206, 212-13 (D.C. Cir. 2017); *Southwood Pharm., Inc.; Revocation of Registration*, 72 Fed. Reg. 36487-01, 36500, 2007 WL 1886484 (DEA July 3, 2007); *see also* Ps' CSA Mem. at 3-6. In 2006 and 2007, the DEA made the duties even clearer.

ARCOS data from 2006 through 2014 shows that the Teva Defendants sold REDACTED MMEs in Cuyahoga and Summit Counties.[109] It was the eighth largest "labeler" during that time frame.[110] Teva employees have acknowledged that the company had a duty to monitor and stop suspicious orders.[111] Yet Teva has never had a system in place to adequately monitor and halt shipments of "Suspicious Orders" to customers.[112]

1. The Teva and Cephalon SOM Systems Violated the Law

Teva states it "complied with all [SOM] and reporting requirements" at all times.[113] But it cites no evidence to support this broad claim. Nor could Defendants find an expert to defend the Cephalon,

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107 Teva Mem., §IV (at 15-17).
108 Teva Mem. at 16-17.
109 *See* McCann Rep., Dkt. #2000-16 at 4 (ranking top 20 labelers form 2006-2014).
110 *Id.*
111 *See* Ex. 112 (McGinn Tr.) at 110:5-131:15,136:15-137:20, 175:3-176:18, 386:2-389:11; Ex. 113 (McGinn Ex. 3); Ex. 114 (Tomkiewicz Tr.) at 174:2-203:6.
112 *See* Report of James E. Rafalski; Dkt. #2000-22 at 179-185.
113 Teva Mem. at 2.

Teva or Actavis Generic Defendants' system.[114] Plaintiffs' expert, James Rafalski, details the systems' failings as fully set forth in Plaintiffs' affirmative summary judgment brief incorporated herein.[115]

Teva's SOM system was wholly deficient. Any time outside entities examined it, the system failed the test. In 2012, Ron Buzzeo, a former DEA agent hired by the Mallinckrodt defendants in this case, advised Teva that its system was "rudimentary," "not sufficiently sensitive . . . to result in any meaningful analysis," and had "no formal Standard Operating Procedures or official guidelines."[116] As Buzzeo noted, to that date, Teva's system had "***never*** identified a suspicious order" and thus "no orders ha[d] ever been reported to the DEA."[117]

Teva, which had $18.8 billion in revenues in 2008, could have hired Buzzeo to implement a compliant system, but instead sought to save about $500,000 by constructing the system "[i]n-[h]ouse."[118] It hired one person (who had no prior experience at a drug manufacturer) to write a SOM system for the entire company. With that one person building it, Teva's system took until August 2014 – almost two years – to implement.[119] And in mid-2015, Teva's own internal audit group found that the SOM system automatically released 95% of all Schedule II products ordered.[120] The 5% of orders held to be investigated were reviewed manually by a single person.[121] The internal audit group itself concluded that Teva's DEA department was not compliant with existing DEA requirements and was at "High" risk for regulatory action.[122]

Further, the new system relied on salespeople who were paid based on volume shipped to investigate whether orders should be considered suspicious. A 2017 PPT by Teva's SOM Manager, Joe

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114 Teva's (and Allergan's) purported expert on SOM systems merely states that he is "not aware of any DEA actions . . . against [any of the moving defendants], at any time related to their suspicious order monitoring obligations." Report of Karl Colder, Dkt. #1939-10 at 34 n.97.

115 Ps' CSA Mem. at 40-43.

116 Ex. 12 (TEVA_MDL_A_01060005) at 005, 007 (Sept. 25, 2012 Buzzeo/Cegedim Report).

117 *Id.* at 005.

118 Ex. 115 (TEVA_MDL_A_01130622) at 11.

119 *See* Ex. 13 (TEVA_MDL_A 02660925); Ex. 14 (TEVA_MDL_A 02660932); Ex. 15 (TEVA_MDL_A 02660892); Ex. 16 (TEVA_MDL_A_01061094).

120 Ex. 17 (TEVA_MDL_A_02475564) at 570.

121 *Id.*

122 *Id.* at 575.

Tomkiewicz, noted ongoing conflicts between his group – DEA compliance – and the Teva sales department.[123] During one exchange, Teva's head of generic sales pressured Tomkiewicz into ultimately releasing a suspicious order, stating: "Publix has 0.8% overall market share and we [Teva] are trying to capture generic oxycodone market share."[124] Tomkiewicz released the order despite having found extensive data that he considered to be "truly indicative . . . of diversionary activity."[125]

Teva argues that it was not required to monitor the "Ohio pharmacies" to which Teva's customers shipped its opioid drugs.[126] But Teva's SOM manager made clear that the company had the capability to monitor pharmacies.[127] Teva certainly had access to "867" invoice-level data and "Chargeback" data allowing it to monitor orders of individual pharmacies and other retailers that were their "customers' customers."[128] Teva certainly could have used the data to diligently flag, report and halt suspicious orders but simply chose not to do so.[129]

Every examination of the SOM system at Teva shows it was set up to fail. As noted above, before September 2012, Teva had ***never*** reported a suspicious order to the DEA.[130] They reported just 12 orders after that (between 2013 and 2017).[131] In 2018, after this action was filed and after greatly expanding its opioid presence with its 2016 purchase of the Actavis generic business, the number jumped to 16 in one year.[132] Even in the face of this extraordinary opioid crisis, Teva maintains essentially the the same deficient SOM system to this day.[133]

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123 Ex. 116 (TEVA_MDL_A_02400068).
124 Ex. 117 (TEVA_MDL_A_02063728).
125 Ex. 114 (Tomkiewicz Tr.) at 440:7-22, 456:4-457:4.
126 Teva Mem. at 16 (emphasis omitted).
127 Ex. 114 (Tomkiewicz Tr.) at 388:7-14.
128 *Id.* at 384:1-389:9.
129 *Id.* at 379:5-380:2.
130 Ex. 12 (MDL_A_01060005) at 005, 007.
131 *See* Ex. 118 (Jan. 7, 2019 Resps. and Objs. to Plaintiffs' 3rd Set of Rogs) at 11 (Resp. to Rog. No. 32). Many of the DEA reports identified in Appendix A appear to be duplicates.
132 *Id.*
133 Ex. 119 (TEVA_MDL_A_01158453); Ex. 120 (TEVA_MDL_A_01158463); Ex. 121 (TEVA_MDL_A_01158470); Ex. 122 (TEVA_MDL_A_01158479) (SOM policies as of June 2018).

2. The Allergan/Actavis Generics Systems Were Worse

Teva's memorandum also asserts that "the Actavis Generic Defendants complied with all [SOM] and reporting requirements."[134] Yet it cites no evidence. In truth, the Actavis SOM systems were worse than the Teva system. Actavis Inc. maintained a SOM system for the Actavis Generic Defendants until early 2013, when Watson Pharmaceuticals Inc. bought Actavis and switched the company to its system. Plaintiffs detail both systems' failings in their affirmative summary judgment brief.[135] Plaintiffs' expert Rafalski also details how the systems did not comply with the relevant law. Similar to Teva's system, Defendants could not find an expert to defend the Actavis Generic Defendants' system. As with Teva's system however, Buzzeo, who has been submitted as a proposed expert on SOM systems by Mallinkcrodt, examined the early Actavis system and gave it failing grades.[136] Later employees of Actavis repeatedly sought to replace their own inadequate system with one designed by Buzzeo's group, but were rebuffed each time by management.[137] Defendants' inability to defend their shambles of a SOM system supports an order denying Defendants' motion.

C. Defendants' Ongoing Violations Have Tolled the SOL

Contrary to Teva's SOL argument, Plaintiffs have documented recent wrongdoing by Teva, both with regard to fraudulent marketing and SOM, much of which is detailed in Plaintiffs' CSA Mem. and in the Rafalski Report. Teva's recent unbranded marketing extended at least into 2015. Thus, Plaintiffs' claims against Teva were timely filed. Plaintiffs hereby incorporate by reference Plaintiffs' Consolidated Memorandum in Opposition to Defendants' Motions for Summary Judgment on Statute of Limitations Grounds.

IV. CONCLUSION

For the reasons set forth above, Plaintiffs respectfully request that Defendants' motion for summary judgment be denied in its entirety.

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134 Teva Mem. at 2.
135 Ps' CSA Mem. at 62-69.
136 *Id.*
137 *Id.*

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